

REMARKS

This communication responds to the final Office Action of March 28, 2006 in which pending claims 1-17 were rejected.

By this communication, claims 1, 5-8, and 16-17 have been amended. The amendments address the claim rejections without adding new matter.

Claims 3 and 4 have been canceled.

New claims 18-21 have been added.

Reconsideration is requested.

Rejections under 35 U.S.C. § 102

Claims 1-6, 12 and 16-17 were rejected under 35 U.S.C. § 102(b) over Vaillancourt (US Patent 5,591,138).

Vaillancourt discloses a protected needle assembly that may include a sheath 17 with a cap 30/32 mounted at the end of a sheath, wherein the cap has a slit 31/33 (Figs. 9 and 10).

For either configuration of cap 30/32, as evidenced by Figs. 9 and 10, Vaillancourt does not disclose each and every element of independent claim 1, as amended, which recites both “a cannula cover that exhibits a substantially closed front facing side comprising a cannula passage opening,” and a “sealing device [] coupled to an interior portion the cannula cover” for sealing the cannula passage opening. This is because if cap 30/32 with slit 31/33 is considered to be a cannula cover, Vaillancourt does not disclose a sealing device; or if cap 30/32 with slit 31/33 is considered to be a sealing device, Vaillancourt does not disclose a cannula cover; but in no case is the Vaillancourt cap 30/32 with a slit 31/33 both a cannula cover and a sealing device.

Even if Vaillancourt is considered to disclose both a passage for a needle and a sealing device for sealing passage, it does not disclose every element of claim 1 because the claim 1 recitation of a sealing element forming a “seal between the cannula and a cannula passage opening” is not present in Vaillancourt. As can be seen in Vaillancourt Figs. 9 and 10, cap 30/32

serves to protect needle 15, but does not form a seal *between* the cannula and a cannula passage opening.

Moreover, Vaillancourt does not disclose a sealing device that exposes a cannula passage opening “via a radial movement of the sealing device away from the center of the cannula passage opening” prior to exposure of the cannula from the cannula cover, as recited by the independent claim.

Because the recitations of at least independent claim 1 as amended, are not present in Vaillancourt, reconsideration and withdrawal of the 102(b) rejection are requested.

Rejections under 35 U.S.C. § 103

Claims 7-11 were rejected under 35 U.S.C. § 103(a) over Vaillancourt in view of Galli (US Patent 5,681,291).

Claims 13-15 were rejected under 35 U.S.C. § 103(a) over Vaillancourt in view of Foster (US Patent 6,217,559).

With respect to the rejection of claims 7-11 over Vaillancourt in view of Galli, Galli does not remedy the deficiencies of Vaillancourt for at least the following reasons.

Galli discloses a disposable auto-injector for prefilled syringes that includes slider 5 (Figs. 1-2 and 4-6), which is a “sliding tubular element.” (Galli, column 5, line 14.) However, Galli does not disclose that slider 5 exhibits “a substantially closed front facing side comprising a cannula passage opening,” as set forth in claim 1.

Even if slider 5 is considered to include a substantially closed front facing side comprising a cannula passage opening, as required by independent claim 1, Galli does not disclose a sealing device coupled to an interior portion a cannula cover which forms a seal between a cannula and a cannula passage opening, as recited in claim 1. Because of this, Galli does not disclose or teach that a sealing device may be configured to expose the needle to the cannula passage opening via a radial movement of the sealing device away from the center of the

cannula passage opening prior to exposure of the cannula from the cannula cover, as recited in claim 1.

Accordingly, the asserted Vaillancourt/Galli combination, even if proper, does not disclose or suggest the recitations of claim 1 or therefore dependent claims 7-11, and the 103 rejection of the claims should be withdrawn.

In addition, combining Vaillancourt and Galli as asserted by the examiner would render Vaillancourt inoperable. Vaillancourt discloses a needle cover *for a needle assembly* where the needle cover is affixed to the needle assembly. Galli, in contrast, discloses a disposable auto-injector for prefilled syringes where the auto-injector incorporates an entire syringe/needle combination within a body (1) and slider (5), where slider (5), operatively *disposed on syringe* (4), slides within body (1) to expose needle (10) of syringe (4). *See Galli Abstract*. Therefore, the combination of the slider (5) operatively mounted on the syringe, from Galli, with the needle cover for the needle assembly of Vaillancourt, would render the function of the *needle cover for the needle assembly* of Vaillancourt inoperable.

Furthermore, with respect to the 103 rejection of Vaillancourt in view of Galli, it is submitted that the Examiner's statement in the Office Action at page 3 is incorrect. The Examiner states: "Regarding claims 7-11, Galli discloses a sealing strip that is slid from the cannula passage opening by a slider that is on the cover (see figures 1-10) in order to make exposing the cannula [sic]. It would have been obvious to one of ordinary skill in the art to modify Vaillancourt with Galli and utilize a slider that removes a sealing strip from the cannula opening in order to quickly and simply expose the cannula as taught by Galli."

Instead, Galli states:

in FIG. 1, the slider 5 covers the whole needle 10, while when completely slid back fully uncovers the same as shown in FIG. 2 (Galli, column 5, lines 20-22).

Thus, it is clear that slider 5 slides from a needle covering position to a needle exposing position. However, Galli does not mention anywhere "a sealing strip that is slid from the cannula passage opening by a slider that is on the cover." Accordingly, it is submitted that because Galli does not

disclose or suggest a sealing strip, the asserted combination of Galli with Vaillancourt is improper.

For at least the preceding reasons § 103 rejection based on the asserted combination of Vaillancourt and Galli should be withdrawn.

With respect to the 103 rejection of claims 13-15 over Vaillancourt in view of Foster, Foster does not remedy the deficiencies of Vaillancourt. Foster discloses an automatic safety syringe construction. Foster does not disclose or suggest a syringe that includes a sealing device that is “coupled to an interior portion the cannula cover and forms a seal between the cannula and the cannula passage opening,” as set forth in independent claim 1, as amended. Because of this, Foster does not disclose or suggest that the sealing device exposes the needle to the cannula passage opening “via a radial movement of the sealing device away from the center of the cannula passage opening prior to exposure of the cannula from the cannula cover,” as recited in claim 1.

It is submitted that Vaillancourt and Foster, alone or in combination, fail to disclose or suggest the recitations of at least independent claim 1, as amended and, therefore dependent claims 13-15. The 103 rejection of the claims should be withdrawn.

As is true of the asserted Vaillancourt/Galli combination, the combination of Vaillancourt with Foster would render Vaillancourt inoperable. Vaillancourt discloses a needle cover *for a needle assembly* where the needle cover is affixed to the needle assembly. Foster discloses an automatic safety syringe construction in which a syringe (20) has sleeve members (30,40) *mounted on the syringe body*, where sleeve member (40) is slidably disposed on syringe for exposing needle (24). Therefore, the combination of the sleeve member (40) operatively mounted on the syringe, from Foster, with the needle cover for the needle assembly of Vaillancourt would render the function of the *needle cover for the needle assembly* of Vaillancourt inoperable.

Additionally, with respect to Foster, the Examiner states: “Foster discloses a syringe with a threaded cover that moves axially (Figures 1-4). It would have been obvious to one of ordinary

skill in the art to modify the cannula system of Vaillancourt and [sic] with the threaded arrangement of Foster in order to securely mount the axial sheath for easy rotational movement.”

However, Foster does not disclose a threaded cover or insert, and instead states that:

The tubular female sleeve member 40 is slidably disposed on the tubular male sleeve member 30. . . . the spring biasing unit 14 comprises a helical spring member 50 dimensioned to surround the male sleeve member 30 and having a lower end 51 which is fixedly secured to the upper end 42 of the female sleeve member 40 and has an upper end 52 which is fixedly secured to the underside of the transverse flange 23 of the syringe member 20. Foster Col. 2, lines 26-35.

For at least the preceding reasons, the 103 rejection of claims 13-15, which depend from amended independent claim 1, should be withdrawn.

#### Dependent Claims

The remaining dependent claims, claims 2-6, 12, 16 and 17, depend directly or indirectly from claim 1 and are allowable for the reasons set forth above, further in view of their additional recitations.

#### New claims

New claims 18-22 are allowable over the art of record for the reasons articulated above with respect to claim 1-6, 12, 16 and 17, and in view of their recitation of a closure moveable to open and close a cannula passage, wherein the movement of the closure comprises a portion of the closure moving in a radial movement away from the center of the cannula passage.

Conclusion

Applicant submits herewith a Request for Continued Examination, and Petition for Extension of time along with the appropriate fees. The Commissioner is hereby authorized to charge any deficiencies to Deposit Account No. 04-1420.

The application now stands in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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Date: \_\_\_\_\_

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By: \_\_\_\_\_

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